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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,378

11/27/2006

David Keith James

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EXAMINER

LAVERT, NICOLE F

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,378	Applicant(s) JAMES ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/5/09, 6/13/08 & 1/30/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 February 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claims 1-11, 18-19, 21-30 & 37-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel (US 4,211,237) in view of Smith et al. (US 2004/0243015)

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Nagel et al. discloses, a method and apparatus for monitoring fetal behaviour comprising (e.g., col 3, line 42): an input for receiving ECG data (e.g., Figure 1, 201) from a set of electrodes attached to a maternal body [e.g., (col 9 & 10, lines 62-68 & 1-4) & (Figure 2, 301-303)]; and a waveform pre-processor (e.g., Figure 3b, 33) for identifying a succession of fetal ECG complex waveforms within the received data; a waveform processor (e.g., Figure 3b, 33) for determining differences in the shapes of a succession of fetal ECG complex waveforms over time (e.g., col 3, lines 45-53). Note that each disclosed QRS complexes of the fetal heart signals comprises of its own shape based on the variations of the QRS of the particular heart beat signals (e.g., col 3, ln 40-53).

Nagel discloses the claimed invention having a method and an apparatus for monitoring fetal behavior by determining difference in shapes of a succession of fetal ECG complex waveforms except wherein said method and apparatus further utilizes an event logger determining a number of changes in fetal spatial presentation or position. Smith et al. teaches that it is known to use a method and apparatus for monitoring the heart-beat of an unborn fetus wherein the said apparatus and method utilize variations in the ECG-morphology of fetal heart-beats observed to indicate the fetal presentation and/or position (e.g., [0001] & [0131]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus as taught by Nagel with the invention of utilizing observed-variations in the ECG-morphology of fetal heart-beats to indicate the fetal presentation and/or position as taught by Smith et al., since such a modification would provide the method and an apparatus for monitoring fetal behavior by determining difference in shapes of a succession of fetal ECG complex waveforms with utilizing an event logger determining a

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number of changes in fetal spatial presentation or position for providing the predictable results pertaining to providing a diagnostics tool in which utilizes observed-fetal presentation and/or position in order to monitor non-invasively the heart-beat of an unborn fetus [e.g., Smith, 0131].

5. **Claims 12-14 & 31-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel (US 4,211,237) and Smith et al. (US 2004/0243015) as applied to claims 1-11 & 22-30 above, and further in view of Beach et al. (US 5,088,498).

Nagel/Smith et al. discloses the claimed invention having a method and an apparatus for monitoring fetal behavior except wherein said method and apparatus further comprises a processing means for detecting phase changes between successive fetal ECG complex waveforms. Beach et al. teaches that it is known to use a phase detector, which determines the approximate phases for ultrasounds reflected at each of several different depths (e.g., col 4, lines 5-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus as taught by Nagel/Smith et al. with the phase detector as taught by Beach et al., since such a modification would provide the method and an apparatus for monitoring fetal behavior with a processing means for detecting phase changes between successive fetal ECG complex waveforms for providing the predictable results pertaining to a providing a precise indication for the distance traveled by the reflective tissue of a fetus (e.g., Beach, col 4, lines 10-11).

6. **Claims 15-17, 20, 34-36 & 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel (US 4,211,237) and Smith et al. (US 2004/0243015) as applied to claims 1-11 & 22-30 above, and further in view of Oriol et al. (US 5,596,993).

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Nagel/Smith et al. discloses the claimed invention having a method and an apparatus for monitoring fetal behavior by determining a difference in fetal complex waveforms except wherein said method and apparatus further comprises a manner in which differences in fetal complex waveforms are detected by change in the positive and/ or negative energy of the fetal ECG complex waveform relative to a reference wherein an alarm is associated with said monitored fetal behavior. Oriol et al. teaches that it is known to use a time plot of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability [e.g., (col 9, lines 60-67) & (Figure 5A)]. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have incorporated the use of a time plot-representation of the baseline heart rate signal, in which the plot shows decelerations associated with loss of variability and a monitoring system, in the system of Nagel et al., as taught by Oriol et al., thereby detecting differences in the fetal complex waveforms by change in the positive and or negative energy of the fetal ECG complex waveform relative to a reference, since such a modification would provide the method and an apparatus for monitoring fetal behavior by determining a difference in fetal complex waveforms in which the differences in fetal complex waveforms are detected by change in the positive and/ or negative energy of the fetal ECG complex waveform relative to a reference for providing the predictable results pertaining to showing the appearance and temporal relations to contractions of a heart rate signal so that a physician can evaluate a newborn's heart rate, and in order to provide output data, such as warnings and recommendation, to the clinician [e.g., Oriol, (col 9, ln 40-42 & 63-67) & (col 19, lines 39-40 & 54-56)].

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Response to Arguments

7. Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762